

-51-

CLAIMS

What is claimed is:

1. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof.
2. The pharmaceutical composition according to claim 1, comprising (*R*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine substantially free of the corresponding (*S*)-enantiomer; or a pharmaceutically acceptable salt thereof.
3. The composition according to claim 2 wherein the amount of (*R*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition is 85% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine.
4. The composition according to claim 3 wherein the amount of (*R*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition is 90% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine.
5. The composition according to claim 4 wherein the amount of (*R*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition is 95% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine.
6. The composition according to claim 5 wherein the amount of (*R*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition

is 99% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine

7. The pharmaceutical composition according to claim 1, comprising (*S*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine substantially free of the corresponding (*R*)-enantiomer; or a pharmaceutically acceptable salt thereof.

8. The composition according to claim 7 wherein the amount of (*S*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition is 85% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine.

9. The composition according to claim 8 wherein the amount of (*S*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition is 90% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine.

10. The composition according to claim 9 wherein the amount of (*S*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition is 95% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine.

11. The composition according to claim 10 wherein the amount of (*S*)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or pharmaceutically acceptable salt thereof, in the composition is 99% by weight or more of the total weight of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine.

12. The pharmaceutical composition according to claim 1, comprising a racemic mixture of the (*R*)- and (*S*)-enantiomers of 1-(3,4-dimethoxyphenyl)-4-

-53-

methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof.

13. A method of treating an leukotriene B₄-mediated inflammatory disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.

14. A method of treating an leukotriene B₄-mediated inflammatory disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 2.

15. A method of treating an leukotriene B₄-mediated inflammatory disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 7.

16. A method of treating an leukotriene B₄-mediated inflammatory disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 12.

17. The method of claim 13 wherein the disorder is selected from the group consisting of inflammatory bowel disease, ulcerative colitis, psoriasis, rheumatoid arthritis, Crohn's Disease and radiation induced gastrointestinal inflammation.

18. A method of preventing or delaying the onset of an inflammatory disorder mediated by leukotriene B₄ in an individual who is at risk of developing an inflammatory disease state, said method comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.

-54-

19. A method of preventing or delaying the onset of an inflammatory disorder mediated by leukotriene B₄ in an individual who is at risk of developing an inflammatory disease state, said method comprising administering to said individual a therapeutically effective amount of the composition according to claim 2.

20. A method of preventing or delaying the onset of an inflammatory disorder mediated by leukotriene B₄ in an individual who is at risk of developing an inflammatory disease state, said method comprising administering to said individual a therapeutically effective amount of the composition according to claim 7.

21. A method of preventing or delaying the onset of an inflammatory disorder mediated by leukotriene B₄ in an individual who is at risk of developing an inflammatory disease state, said method comprising administering to said individual a therapeutically effective amount of the composition according to claim 12.

22. A method of treating an thromboxane A₂-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.

23. A method of treating an thromboxane A₂-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 2.

24. A method of treating an thromboxane A₂-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 7.

25. A method of treating an thromboxane A₂-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 12.

26. The method according to claim 22 wherein the thromboxane A₂-mediated disorder is a chronic inflammatory disorder.

27. The method according to claim 26 wherein the chronic inflammatory disorder is selected from the group consisting of chronic fatigue syndrome/fibromyalgia, infertility, osteonecrosis of the jaw, multiple sclerosis, depression, autism, Crohn's Disease, Inflammatory Bowel Disease, late Lyme Disease, Sjogren's Syndrome, transient ischemic attack, attention deficit disorder and Parkinson's Disease.

28. The method according to claim 22 wherein the disorder mediated by thromboxane A₂ involves an immune system activation of coagulation.

29. The method according to claim 22 wherein the disorder mediated by thromboxane A₂ is pain.

30. The method according to claim 22 wherein the disorder mediated by thromboxane A₂ is asthma.

31. The method according to claim 22 wherein the disorder mediated by thromboxane A₂ is angiogenesis associated with a developing tumor.

32. A method of preventing or delaying the onset of a thromboxane A₂-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.

33. A method of treating an adenosine-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.

-56-

34. A method of treating an adenosine-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 2.

35. A method of treating an adenosine-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 7.

36. A method of treating an adenosine-mediated disorder in an individual in need of such treatment, comprising administering to said individual a therapeutically effective amount of the composition according to claim 12.

37. The method according to claim 33 wherein the disorder mediated by adenosine is a central nervous system disorder associated with elevated electrical excitability of neurons.

38. The method according to claim 37 wherein the central nervous system disorder is epilepsy.

39. The method according to claim 33 wherein the disorder mediated by adenosine is a central nervous system disorder associated with decreased cerebral blood flow.

40. The method according to claim 33 wherein the disorder mediated by adenosine is a central nervous system disorder associated with increased release of excitatory amino acids.

41. The method according to claim 39 or claim 40 wherein the central nervous system disorder is stroke.

42. The method according to claim 33 wherein the disorder mediated by adenosine is cerebral ischemia.

43. The method according to claim 33 wherein the disorder mediated by adenosine is neuronal cell death associated with adenosine mediated cerebral ischemia or stroke.

-57-

44. The method according to claim 33 wherein the disorder mediated by adenosine is migraine.
45. The method according to claim 33 wherein the disorder mediated by adenosine is Parkinson's Disease.
46. The method according to claim 33 wherein the disorder mediated by adenosine is congestive heart failure.
47. The method according to claim 33 wherein the disorder mediated by adenosine is coronary artery disease.
48. The method according to claim 33 wherein the disorder mediated by adenosine is a hypertension.
49. The method according to claim 33 wherein the disorder mediated by adenosine is renal failure.
50. The method according to claim 33 wherein the disorder mediated by adenosine is glaucoma.
51. The method according to claim 33 wherein the disorder mediated by adenosine is asthma.
52. The method according to claim 33 wherein the disorder mediated by adenosine is myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy.
53. The method according to claim 33 wherein the disorder mediated by adenosine is a chronic inflammatory disorder.
54. A method of enhancing wound healing, said method comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.

-58-

55. A method according to claim 54 of enhancing wound healing in advance of a surgical procedure.

56. A method of inducing gastrointestinal relaxation in an individual in need of such treatment, said method comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.

57. A method according to claim 56 wherein said individual is suffering from irritable bowel syndrome

58. A method of preventing, reducing or delaying the onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy in an individual who is at risk of developing such myelosuppression due to the present or imminent administration to said individual of cytotoxic chemotherapy or ionizing radiation therapy, said method comprising administering to said individual a therapeutically effective amount of the composition according to claim 1.